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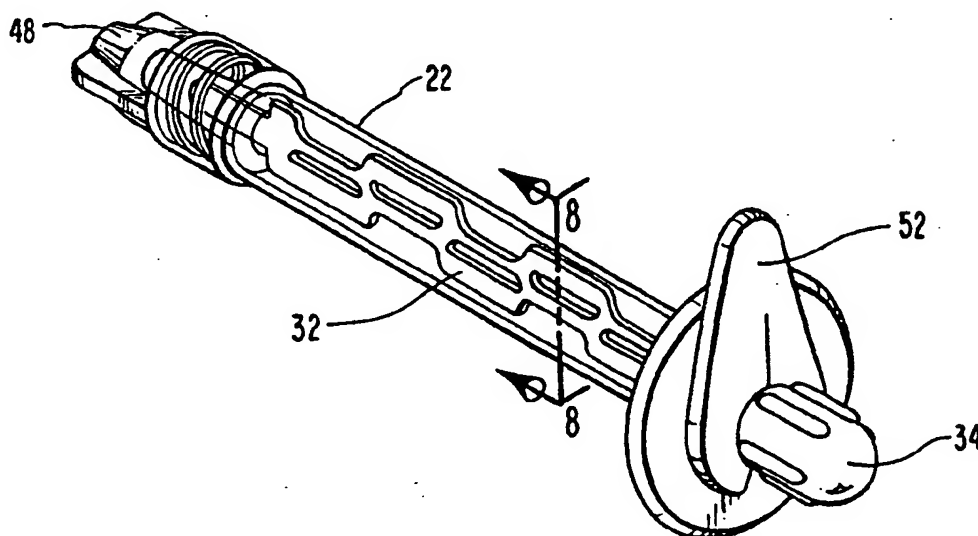
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## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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<p>(21) International Application Number: <b>PCT/US94/09983</b></p> <p>(22) International Filing Date: 2 September 1994 (02.09.94)</p> <p>(30) Priority Data:              08/117,217      3 September 1993 (03.09.93)      US              08/270,924      5 July 1994 (05.07.94)      US</p> <p>(71) Applicant: <b>ULTRADENT PRODUCTS, INC. [US/US]; 505 West 10200 South, South Jordan, UT 84065 (US).</b></p> <p>(72) Inventor: <b>FISHER, Dan, E.; 10444 South Dimple Dell Road, Sandy, UT 84093 (US).</b></p> <p>(74) Agents: <b>NYDEGGER, Rick, D. et al.; Workman, Nydegger &amp; Seeley, 60 East South Temple, 1000 Eagle Gate Tower, Salt Lake City, UT 84111 (US).</b></p>	<p>(81) Designated States: <b>AU, CA, JP, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).</b></p> <p><b>Published</b>  <i>With international search report.</i></p>	

(54) Title: METHODS AND APPARATUS FOR MIXING AND DISPENSING MULTI-PART COMPOSITIONS



## (57) Abstract

Methods and apparatus are provided for mixing and dispensing multi-component compositions. The preferred embodiment utilizes a syringe barrel (22) as a mixing chamber and for dispensing of the mixed components. A mixer element, preferably including a paddle member (32) and finger grip means (34) for rotating the paddle member (32), is provided for insertion into the syringe barrel (22) to effect the desired mixing. A scraper element (52) is used to scrape mixed components from the mixer element so as to retain the mixed components within the syringe barrel (22) upon removal of the paddle member (32) after mixing is completed. Mixing is preferably performed with the multiple components placed in side-by-side orientation within the syringe barrel (22) rather than one on top of another.

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## METHODS AND APPARATUS FOR MIXING AND DISPENSING MULTI-PART COMPOSITIONS

### BACKGROUND OF THE INVENTION

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#### Technical Field

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The present invention relates to methods and apparatus for use in mixing and dispensing multi-component compositions such as dental cements or impression materials. More particularly, the present invention is directed to syringe mixing and dispensing methods and apparatus.

15

#### Background Information:

Many modern formulations are packaged in two parts, often known as A and B components. Upon mixing, these A and B components typically undergo a chemical reaction which causes the resultant composition to "set up" in some desired manner.

In the dental field, for example, several two-part formulations currently enjoy wide use. Glass ionomer cements and resinous luting cements are frequently used for applications such as securing dental caps in place. Dental impressions are made using A and B components.

20

In order to work properly, it is important that the A and B components of these two component systems be mixed together rapidly and thoroughly and in the right proportions. Failure to mix rapidly can result in loss of valuable working time with the resultant composition, and can impact the ability to obtain a thorough mix as the composition begins to set up unevenly. Failure to mix thoroughly can result in a composition having less than optimum characteristics. For example, if a poorly mixed composition is used as a cement, it is possible that portions of the cement will fail to reach the chemical strength required for a long-term bond.

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Problems of obtaining rapid and uniform mixing are often complicated by differences in the A and B components. Sometimes it is necessary to mix two liquids, while other times it is necessary to mix a powder with a liquid. Sometimes there are equal amounts of the A and B components, but other times there is more of one component than another. Sometimes the two components have similar viscosities, while at other times the two components have widely differing viscosities.

The primary means employed for mixing A and B components has been simple mechanical mixing, such as by means of a mixing bowl or pad and a stir instrument such as a spatula. This method tends to be somewhat messy and time consuming. It is difficult at times to gauge whether the mixing has been sufficiently thorough.

5 It is also difficult in some instances to prevent formation of small air bubbles in the mixed composition. During the mixing process itself, the stirring action of the spatula, or similar mixing instrument, introduces and causes air bubbles to be entrapped within the mixed composition. Further, most dental compositions are ultimately dispensed from a syringe in order to control the amount dispensed, to permit precise  
10 placement of the dental composition, and to prevent premature evaporation of constituents of the composition. This generally requires placement of the mixed compositions into a syringe. Additional air can become entrained during this step. Entrained air bubbles are usually detrimental.

Further, the simple process of mixing the components on a pad or in a bowl and  
15 then transferring them to a syringe takes time; this can lessen the available working time to actually utilize the composition. It is not uncommon for so much time to pass during the mixing and syringe-loading steps that the mixed composition becomes effectively unusable.

In an effort to overcome the time delays and the mess inherent in the approach set  
20 forth above involving mixing on a pad or in a bowl followed by loading into a syringe, attempts have been made to mix materials directly from a syringe or from a caulking gun. These attempts have involved the use of specially formed tips which effect some mixing as material is dispensed from the syringe or caulking gun. Although useful from the standpoint of minimizing the amount of time used to effect the mixing of A and B  
25 components, incomplete mixing is common. Furthermore, the mixing tips utilized are frequently expensive, and are difficult to reuse.

### SUMMARY OF THE INVENTION

Additional advantages of the invention are set forth hereinbelow in the detailed  
30 description, or will be appreciated by the practice of the invention.

In accordance with the invention as embodied and broadly described herein, the present invention utilizes a syringe barrel as a mixing chamber and for dispensing of the mixed components.

5 A mixer element, preferable comprised of a paddle member and a finger grip means for rotating the paddle member, is provided for insertion into the syringe barrel to effect the required mixing.

Mixing is preferably performed with the multiple components placed in side-by-side orientation within the syringe barrel rather than one on top of another.

10 After mixing, the mixer element is removed and a plunger element inserted for use in dispensing material from the syringe barrel in conventional fashion. A scraper element is used to scrape mixed material from the paddle member in order to retain the material within the syringe barrel upon removal of the mixer element.

15 In an alternative embodiment, the plunger is equipped with a detachable piston. After mixing, the piston, which has a vent hole formed through its center, is separately placed within the barrel and advanced up to the mixed material. In this way, air is vented from within the barrel through the vent hole. Thereafter, the plunger element is inserted in a manner so as to seal the vent hole, and the syringe is then used to dispense the material in conventional fashion.

## 20 BRIEF DESCRIPTION OF THE DRAWINGS

In the accompanying drawings, which represent the best mode presently contemplated for carrying out the present invention:

Figure 1 is a perspective view of a syringe assembly suitable for use in mixing and delivering a multi-part composition.

25 Figure 2 is a perspective view of the syringe barrel component of the syringe assembly of Figure 1.

Figure 3 is an elevation view of a presently preferred embodiment of a mixer element used to effect mixing of multi-part compositions.

30 Figure 4 is a perspective view of a multi-syringe device for use in introducing two components of a two-part composition into a syringe barrel such as that shown in Figure 2 for mixing in accordance with the present invention.

Figure 5 is a perspective view of one presently preferred embodiment of a scraper element for use with a mixer element following mixing.

Figure 6 is a perspective view of the reverse side of the scraper element of Figure 5.

5 Figure 7 is a perspective view of the mixer element of Figure 3 mounted together with the syringe barrel of Figure 2 and the scraper element of Figures 5 and 6.

Figure 8 is a cross-sectional view taken along the lines 8-8 of Figure 7, showing in schematic form by the use of arrows one manner in which mixing occurs.

Figure 9 is an elevation view of an alternative embodiment of a mixer element.

10 Figure 10 is a perspective view of a syringe barrel having a chevron shaped hole shown together with the mixer element of Figure 5.

Figure 11 is a side elevation view of a scraper element suitable for use with the syringe barrel of Figure 10.

Figure 12 is an end elevation view of the scraper element of Figure 11.

15 Figure 13 is an exploded perspective view of an alternative embodiment of the syringe assembly.

Figure 14 is a perspective view of the syringe assembly of Figure 13, showing the manner by which the piston is advanced within the syringe barrel so as to vent air from contained within the barrel.

20 Figure 15 is a cross-sectional view taken along lines 15-15 of Figure 14.

Figure 16 is a perspective view of the syringe assembly of Figure 13, showing the interconnection of the syringe plunger and plunger piston for subsequent delivery of the mixed composition.

## 25 DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

The present invention is directed to methods and apparatus for mixing and dispensing multi-component compositions such as dental cements or impression materials. More particularly, the present invention is directed to a syringe mixing and dispensing system useful for rapid and complete mixing of multi-component  
30 compositions and subsequent dispensing of the mixed composition.

Figure 1 illustrates a syringe assembly 10 useful for dispensing compositions, such as dental cements and bonding materials in accordance with the present invention. Syringe assembly 10 includes a syringe barrel 22 fitted with a plunger element 24 of conventional design for delivery of material contained within the syringe barrel through a tip 26. Tip 26 may be of any suitable design for use in particular applications, but is shown as having a structure useful for dispensing dental compositions. Although the remainder of the discussion will be directed to uses of the present invention for mixing and dispensing dental compositions, it should be understood that other materials may be mixed and dispensed using the methods and apparatus disclosed and claimed herein.

Figure 2 separately illustrates the syringe barrel 22 of Figure 1. It is preferred that syringe barrel 22 be provided with a hole 28, which acts as a means for venting air contained within the syringe barrel 22 when plunger element 24 is inserted into the syringe barrel after mixing. When material contained within syringe barrel 22 is packed from the discharge end, hole 28 should be located at a position substantially level with the end which will be in contact with plunger element 24. Placing hole 28 higher along the length of syringe barrel 22 will result in retaining air within the syringe barrel, possibly resulting in entrainment of air bubbles during use of syringe assembly 10 to dispense material. Placing hole 28 lower along the length of the syringe barrel will result in leakage of material through the hole upon application of pressure to plunger element 24 to dispense material from syringe assembly 10. Accordingly, it may be desirable to cut hole 28 at the time of use in order to accommodate a particular volume of material desired to be mixed and dispensed, or it may be desirable to provide previously prepared syringe barrels having holes in different locations marked with the optimum volume of material with which it is to be used for mixing and dispensing. It is anticipated that syringe barrels will be provided together with the components of a multi-component composition to be mixed therein and dispensed therefrom, and hence will be provided with a hole 28 located at an optimal location.

An important feature of the present invention is the provision of mixing means for mixing material placed within syringe barrel 22. A presently preferred embodiment of mixing means is mixer element 30 illustrated in Figure 3. Mixer element 30 includes an elongate paddle member 32 having a length substantially the same as that of syringe



barrel 22 with which it will be used. The width of paddle member 32 is preferably about the same as the internal diameter of the syringe barrel so as to effect more complete mixing by scraping material from the wall of the syringe barrel so that it mixes with remaining material contained within the barrel.

5           Various configurations of paddle members can be used to effect mixing of material contained within the syringe barrel. As illustrated in Figure 3, it is presently preferred that paddle member 32 be provided with a plurality of generally "D" shaped internal cutouts 32A from the body of the paddle member, and additional generally "D" shaped edge cutouts 32B from the sides thereof. The use of cutouts 32A and 32B assist  
10           in generating turbulence as the paddle member is rotated, as discussed below. Although cutouts 32A and 32B are shown along the length of paddle member 32, it should be understood that cutouts are used only in the region where mixing occurs. Hence, if only a small volume is mixed, it may be desirable to provide cutouts only near the end of the paddle member.

15           Mixer element 30 is also advantageously provided with a finger grip member 34 which serves as means for rotating the paddle member so as to effect mixing of material contained within the syringe barrel.

          It is frequently desirable to mix together various components of multi-component compositions, such as some dental cements and bonding materials. For purposes of  
20           brevity, the discussion contained herein shall be principally directed to the use of two-component systems, sometimes referred to as A and B component systems. Nevertheless, it should be understood that the methods and apparatus of the present invention will accommodate systems having more than two components.

          The rotation of mixer element 30 within syringe barrel 22 has been found to be  
25           quite effective in mixing A and B components rapidly and completely. It has been determined that the most effective mixing of the A and B components utilizing the apparatus of the invention is accomplished by loading the two components side-by-side within the syringe barrel rather than one on top of the other. Side-by-side loading may be advantageously performed by use of a two-syringe device 36 such as that shown in  
30           Figure 4. Figure 4 illustrates the use of two syringe barrels 38A and 38B coupled together by clamps 40A, 40B and 40C. The output ends of syringe barrels 38A and 38B

are fitted with tips 42A and 42B adapted at one end to secure to the syringe barrel and provided at the other end with tubing members 44A and 44B, respectively. Collar 46 is used to secure tubing members 44A and 44B together, with both tubing members terminating at the same position.

5           Prior to use, the syringe barrels 38A and 38B of Figure 4 are filled with A and B components, respectively, of a two-component composition. The output end of syringe barrel 22 is sealed with a cap, such as the cap 48 illustrated in Figure 7. The output ends of tubing members 44A and 44B are inserted within syringe barrel 22 as far as possible, so that material will be dispensed therefrom near the output end of syringe barrel 22.

10          Then, the two plungers 50A and 50B are simultaneously depressed while slowly withdrawing tubing members 44A and 44B from within syringe barrel 22. This results in placement of material from each of syringe barrels 38A and 38B side-by-side within syringe barrel 22.

          It should be understood that additional syringe barrels 38 and associated elements

15          could be added to the device of Figure 4 in order to accommodate more than two components. Further, the diameters of syringe barrels 38A and 38B could be altered as necessary to effect differing ratios of A and B components. For example, if A and B components are to be added in substantially equal amounts, both syringe barrels 38A and 38B would be substantially identical. If, however, it were desired to add two parts of A

20          to one part of B, syringe barrel 38A should have a cross-sectional area twice that of syringe barrel 38B. It will be appreciated that other modifications could be made in the respective sizes of syringe barrels 38A and 38B to accommodate other mixing ratios. Markings on the sides of syringe barrels 38A and 38B can be used to measure a desired volume to be introduced into syringe barrel 22, or one could look at markings optionally

25          provided on syringe barrel 22 or the location of hole 28 to measure the desired amount of the A and B components.

          After the A and B components are loaded in side-by-side fashion within syringe barrel 22 using a method such as that discussed above, mixing is accomplished by inserting mixer element 30 within syringe barrel 22, such as illustrated in Figure 7.

30          A feature of the apparatus of the present invention is the provision of scraper means for removing material from the surface of the paddle member of mixer element

30 after mixing is completed. One presently preferred embodiment of suitable scraper means is scraper element 52, illustrated alone in Figures 5 and 6, and in combination with other elements of the present invention in Figure 8.

5 As best seen in Figure 6, the underside of scraper element 52 is preferably provided with a cylindrical plug member 52A adapted to fit securely within syringe barrel 22. A slot 52B is provided through scraper element, having substantially the same dimensions as the width and thickness of paddle member 32. Prior to use, the paddle member is inserted into slot 52B all the way to the finger grip member, and the combination of the scraper element 52 and mixer element 30 is then secured to syringe  
10 barrel 22, as illustrated in Figure 7. It may be desirable to provide scraper element 52 with a slit 52C and a notch 52D to make easier the task of introducing and removing the paddle member from slot 52B.

Mixing of material contained with syringe barrel 22 is accomplished by rotating mixer element 30. Scraper element 52 will rotate together with the mixer element,  
15 making it possible to use the scraper element as the means for rotating the paddle member and to omit the use of separate finger grip member 34.

The provision of cutouts 32A and 32B generate turbulence as mixer element 30 is rotated; such cutouts function as means for effecting turbulence within the syringe barrel in order to obtain more rapid and complete mixing. Such mixing can be  
20 accomplished with little or no entrainment of air bubbles. Figure 8 illustrates in schematic form the generation of turbulence in response to rotation of paddle member 32. After mixing is complete, mixer element 30 is withdrawn from the syringe barrel while maintaining the scraper element in place. This serves to contain material within syringe barrel 22. After removing the mixer element, the scraper element may be removed and  
25 plunger element 24 fitted in place for use in dispensing material from syringe barrel 22. Cap 48 may be removed and replaced with tip 26.

It is to be understood that alternative forms of the elements of the apparatus of the present invention may be made as long as the broad functions set forth above are preserved. For example, Figure 9 illustrates an alternative embodiment of a mixer  
30 element 130. One of ordinary skill will be able to envision many other workable alterations in light of the teachings herein.

Another presently preferred embodiment of the present invention which differs in construction but not function from the discussion set forth above is illustrated in Figures 10-12. Figure 10 illustrates a syringe barrel 122 having a means for venting air contained within the syringe barrel which is comprised of a generally chevron-shaped hole 128. It is seen that paddle member 30 bisects the center of the chevron. A scraper element 152 (Figures 11 and 12) is formed so as to include a pair of projecting fingers 152A and 152B adapted to pass through hole 128 and embrace paddle member 32. A knob 152C is used for grasping scraper element 152 for placement of finger 152A and 152B through hole 128 and later removal of the scraper member. Preferably, the outer ends of fingers 152A and 152B are cut so as to fit snugly against the far wall of syringe barrel 122 when the scraper element is inserted, so that the syringe barrel provides support to the fingers during removal of the mixer element.

Unlike scraper member 52, which is connected to mixer element 30 prior to mixing and rotates together with the mixer element, scraper 152 does not rotate with the mixer element. Accordingly, when using a scraper element of the general type shown in Figures 10-12, the scraper element is set aside until after mixing is complete. At that time, the scraper element is inserted through hole 128. The mixer element is then removed, followed by removal of the scraper element and insertion of a plunger element for use in dispensing material from within the syringe barrel.

Once again, it is to be emphasized that other alterations are contemplated within the scope of the present invention. For example, the means for venting air contained within the syringe barrel 22 could be a substantially straight hole in place of the chevron-shaped hole of Figure 10, together with corresponding changes to the scraper element.

Yet another presently preferred embodiment of the present invention is illustrated in Figures 13 through 16. Figure 13 illustrates a syringe assembly, designated generally at 10a, which can also be used for dispensing compositions, such as dental cements and bonding materials. Although syringe assembly 10a performs the same function as the previous embodiments, it differs in construction and is used in a slightly different manner.

As is shown in Figure 13, syringe assembly 10a includes a syringe barrel 222 fitted with a plunger element 224 for delivery of material contained within the syringe

barrel through a delivery tip (not shown). As with the embodiment of Figure 1, the delivery tip may be of any suitable design for use in particular applications. As is further shown in Figure 13, syringe assembly 10 also includes a piston means for advancing the multi-component composition within the barrel through the delivery tip, such as piston 230. Piston 230 is preferably cylindrical in shape, formed from an elastomeric rubber material and is sized so as to be received within syringe barrel 222 in a tight-fitting yet moveable manner. Piston 230 further includes a means for venting air contained within the syringe barrel before the multi-component composition is dispensed, such as a vent hole 232. Vent hole 232 is formed completely through the center longitudinal portion of the piston 230, as is shown in the cross-sectional view of Figure 15.

With continued reference to Figure 13, formed at the distal end of plunger element 224 is a tapered tip 234. The tapered tip 234 and the vent hole 232 are sized such that, in combination with the elastomeric properties of the piston 230, the tapered tip 234 is capable of being received in a substantially airtight fashion within the vent hole 232. When received within the vent hole 232, the plunger 224 and piston 230 assembly together can be used for delivery of material contained within the syringe barrel through tip 226 in a conventional manner.

Unlike the syringe barrel 22 illustrated in Figure 1, which has a hole 28 formed therein as a means for venting air, syringe barrel 222 does not have a hole formed in it. Instead, in the embodiment of Figure 13, the vent hole 232 that is formed within the piston 230 acts as a means for venting air from within the syringe barrel after mixing and before delivery of material 232 contained within the syringe barrel 222 is commenced. This insures that air bubbles are not present within the mixed composition.

The manner by which air is vented from within the syringe barrel 222 is illustrated in Figures 14 and 15. Once the various components have been placed within the syringe barrel 222 in the side-by-side manner, and then mixed as described above, the piston 230 is separately inserted into the syringe barrel 222. The distal end 236 of tapered tip 234 is then placed on the top surface 238 of piston 230 in a manner so as to leave the vent hole 232 unobstructed, as is shown in Figures 14 and 15. The plunger element 224 is then used to press against the piston 230 and thereby advance it through

the syringe barrel 222, until the bottom surface 240 of the piston 230 is in contact with material contained within the barrel 222.

As the piston 230 is advanced through the syringe barrel 222, any air contained within the barrel is expressed through the piston's vent hole 232. To insure that air is not entrained within the syringe barrel 222, the bottom surface 240 of piston 230 should be advanced right up to the point where the material (shown as 242 in Figure 15) has been filled within the barrel 222. Further advancement of the piston 230 should be avoided at this point, so as to prevent material 242 contained within the barrel from being expressed through the vent hole 232.

By advancing the piston 230 in this manner, all air contained within the barrel 222 will have been expressed, thereby avoiding the entrainment of air bubbles during use of the syringe assembly 10a when dispensing the material. Having expressed the air, the syringe assembly 10a can thereafter be used as a conventional syringe, as is illustrated in Figure 16. Thus, when piston 230 is positioned against the material contained within the barrel 222, the tapered tip 234 is placed within the vent hole 232 of the piston 230, thereby sealing the vent hole 232. Thereafter, syringe assembly 10a can be used to dispense of the material through the delivery tip 226 by advancing syringe plunger 224 and piston 230 assembly. Importantly, since the tapered tip 234 is received within the vent hole 232 in a substantially air-tight fashion, material does not leak through the vent hole 232 as pressure is created within the syringe barrel 222 when the plunger 224 is advanced.

As will be appreciated, utilizing a vent hole 232 in combination with piston 230 as a means for venting air from within the syringe barrel 222 eliminates the need for forming a hole in the side of the syringe barrel (as is shown and described in connection with Figure 1 above). As such, any required amount of material for a given application may be placed and mixed within the syringe barrel 222, and there is no longer the need to be concerned with whether the material will leak through a hole formed in the barrel, as discussed above in connection with the embodiment of Figure 1. This eliminates the need for cutting hole 28 at the time of use, or for providing previously prepared syringe barrels having holes in different locations for different applications.

From the foregoing, it may be seen that the present invention provides improved methods and apparatus for mixing and dispensing multi-component compositions. Unlike conventional syringe-mixing systems, the present invention achieves rapid and thorough mixing while substantially preventing the entrainment of air bubbles in the mixed compositions. Further, by achieving the mixing within a syringe barrel, the methods and apparatus of the present invention permit direct and easy dispensing of mixed materials.

It will be appreciated that the present invention may be embodied in other specific forms without departing from its spirit or essential characteristics. The described embodiments are to be considered in all respects only as illustrative and not restrictive, and the scope of the invention is indicated by the appended claims rather than by the foregoing description. All changes which come within the meaning and range of equivalency of the claims are to be embraced within their scope.

What is claimed is:

1. A system for mixing and dispensing multi-component compositions, said system comprising:

a syringe barrel for receiving multiple components to be mixed;

5 mixing means for mixing said components within the syringe barrel, said mixing means including

an elongate paddle member for insertion into said syringe barrel

and

10 means for rotating said paddle member within the syringe barrel so as to effect mixing of components contained therein;

scraper means for removing said components from the surface of the paddle member so as to retain the components within the syringe barrel upon removal of the paddle member after mixing is completed.

15 2. A system for mixing and dispensing multi-component compositions as defined in claim 1, wherein the paddle means is dimensioned so as to extend in length substantially the whole length of the interior of the syringe barrel and in width substantially across the diameter of the interior of the syringe barrel.

20 3. A system for mixing and dispensing multi-component compositions as defined in claim 1, wherein the paddle means is provided with means for effecting turbulence in order to assist in mixing components within the syringe barrel.

25 4. A system for mixing and dispensing multi-component compositions as defined in claim 3, wherein the means for effecting turbulence comprises cutouts in the paddle member.

30 5. A system for mixing and dispensing multi-component compositions as defined in claim 4, wherein the cutouts in the paddle member are generally "D" shaped.



6. A system for mixing and dispensing multi-component compositions as defined in claim 4, wherein cutouts are provided on the edge of the paddle member and internally of the edge thereof.

5 7. A system for mixing and dispensing multi-component compositions as defined in claim 1 wherein the scraper means comprises a scraper element having a plug member for placement into the end of the syringe barrel, and a slot for receiving the mixing element.

10 8. A system for mixing and dispensing multi-component compositions as defined in claim 1, further comprising a hole on the side of the syringe barrel from the interior to the exterior thereof for exhausting air from said syringe barrel upon insertion of a plunger element into said syringe barrel for use in dispensing material contained therein.

15 9. A system for mixing and dispensing multi-component compositions as defined in claim 8, wherein the hole is elongated, and wherein the scraper means comprises a scraper element having two projecting fingers for insertion through said hole and on opposite sides of the mixing element, thereby serving to scrape material from the  
20 mixing element as said mixing element is removed.

10. A system for mixing and dispensing multi-component compositions as defined in claim 1, wherein the means for rotating the paddle member within the syringe barrel comprises a finger grip member secured to the end of the paddle member.

25 11. A system for mixing and dispensing multi-component compositions as defined in claim 1, further comprising piston means for advancing the multi-component composition contained within the barrel, the piston means including means for venting air contained within the syringe barrel before the multi-component composition is  
30 dispensed.

12. A system for mixing and dispensing multi-component compositions as defined in claim 11, wherein the piston means is comprised of a cylindrically shaped rubber piston.

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13. A system for mixing and dispensing multi-component compositions as defined in claim 11, wherein the venting means comprises a vent hole that is formed through the piston means, whereby said air contained within the syringe barrel is vented through the vent hole as the piston means is advanced through the syringe barrel.

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14. A system for mixing and dispensing multi-component compositions as defined in claim 13, wherein the vent hole is sized so as to be capable of receiving in a substantially air-tight fashion a distal tip end of a plunger element that is inserted into the syringe barrel for use in dispensing material contained therein.

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15. A system for mixing and dispensing multi-component compositions as defined in claim 14, wherein the distal tip end of the plunger element has a tapered shape.

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16. A method for mixing at least two components so as to form a multi-component composition, comprising the steps of:

simultaneously placing, in a side-by-side orientation, a predetermined amount of the at least two components into a dispensing barrel of a dispensing syringe; and

25

utilizing a paddle member to mix the at least two components contained within the dispensing barrel of the dispensing syringe in a manner such that the mixing occurs simultaneously along the entire length of the dispensing barrel, thereby resulting in the multi-component composition.

30

17. A method as defined in claim 16, wherein the placement step comprises the steps of:

introducing a predetermined amount of each component separately into respective syringe barrels of a multi-syringe device having a plurality of syringe barrels, wherein each syringe barrel has a plunger disposable therein and each barrel further has respective output ends that are oriented so as to be coextensive with one another;

placing the coextensive output ends within the dispensing syringe barrel;  
and

injecting the components into the dispensing syringe barrel from the coextensive output ends by depressing each of the multi-syringe plungers, thereby resulting in the placement of the at least two components within the dispensing syringe barrel in a side-by-side orientation.

18. A method as defined in claim 17, comprising the additional step of slowly retracting the coextensive output ends from within the distal end of the dispensing syringe barrel toward the proximate end of the dispensing syringe barrel to a predetermined fill-point, and wherein the retraction step occurs simultaneously with the injection step.

19. A method as defined in claim 18, wherein each of the plungers of the multi-syringe device are simultaneously depressed while performing the injection step.

20. A method as defined in claim 16, wherein the mixing step comprises the steps of:

inserting the paddle member into the dispensing syringe barrel;

rotating the paddle member within the dispensing syringe barrel so as to effect mixing of the components simultaneously along the entire length of the dispensing barrel; and

removing the paddle member from within the dispensing syringe barrel.

21. A method as defined in claim 16, further comprising a scraping step, wherein a scraper is utilized to remove the components from the surface of the paddle

member when the paddle member is removed from the dispensing syringe barrel after the mixing step is complete so as to retain the components within the dispensing syringe barrel.

5           22.    A method as defined in claim 16, further comprising an air removal step following the mixing step, wherein air contained within the dispensing syringe barrel is removed so as to prevent the entrainment of air bubbles in the mixed composition.

10           23.    A method as defined in claim 22, wherein the air removal step comprises the steps of:

              placing a plunger piston into the dispensing syringe barrel, the plunger piston having a vent hole formed therein;

              advancing the plunger piston through the dispensing syringe barrel up to the mixed composition contained therein, whereby excess air contained within the syringe barrel is thereby displaced and vented through said vent hole; and

15           inserting a plunger element into the dispensing syringe barrel, the distal end of the plunger element being received within said vent hole and forming a substantially air-tight seal.

20           24.    A method as defined in claim 23, wherein the plunger piston is advanced through the dispensing syringe barrel by pressing on the piston with the distal end of the plunger element in a manner so as to not obstruct the vent hole.

25           25.    A method for mixing at least two components so as to form a multi-component composition, comprising the steps of:

              simultaneously placing, in a side-by-side orientation, a predetermined amount of the at least two components into a dispensing barrel of a dispensing syringe;

              inserting a paddle member into the dispensing syringe barrel;

30           rotating the paddle member within the dispensing syringe barrel so as to effect the simultaneous mixing of the components along the entire length of the

dispensing syringe barrel and thereby resulting in the multi-component composition;

removing the paddle member from within the dispensing syringe barrel;

and

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removing air from within the dispensing syringe barrel so as to prevent the entrainment of air bubbles in the mixed composition.

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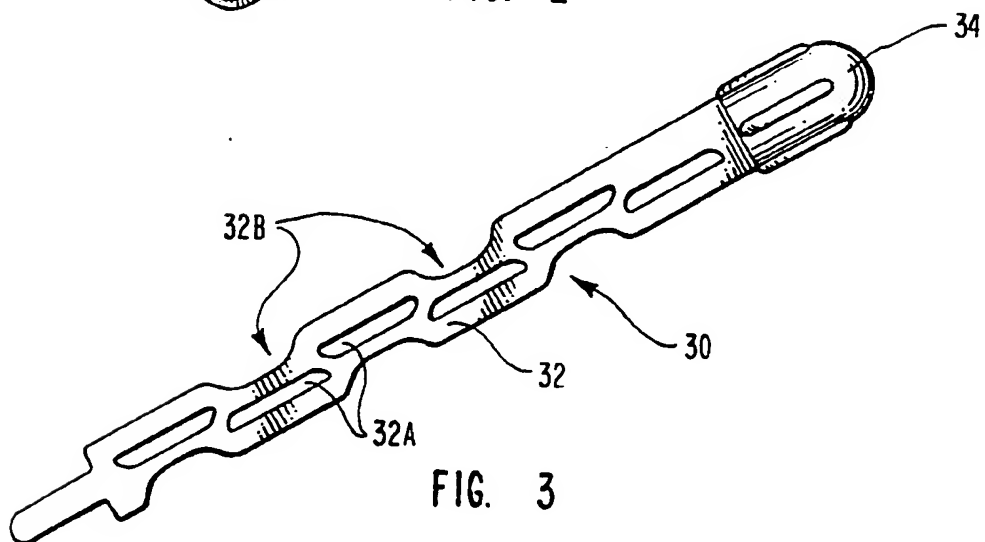
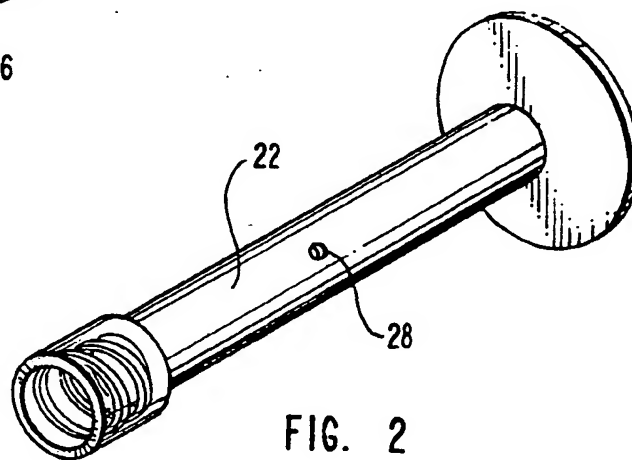
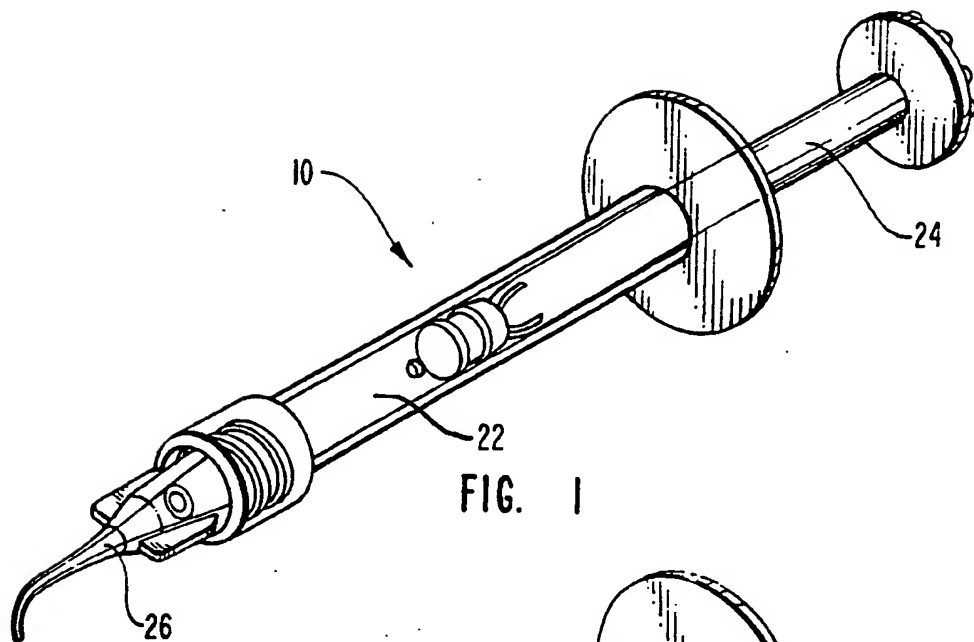
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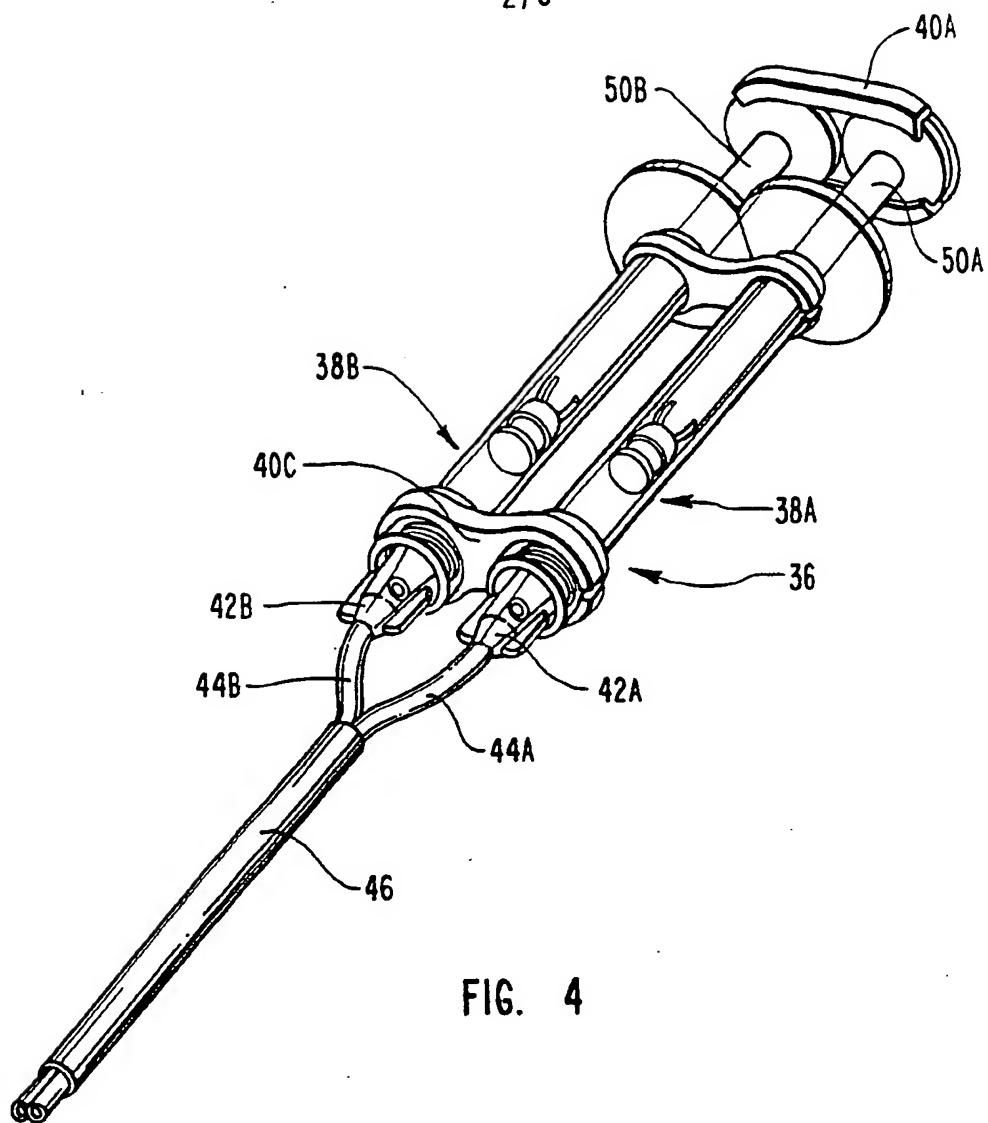


FIG. 4

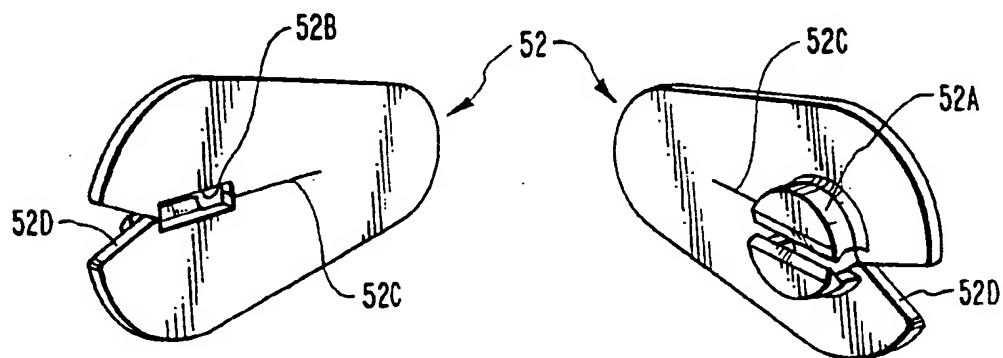
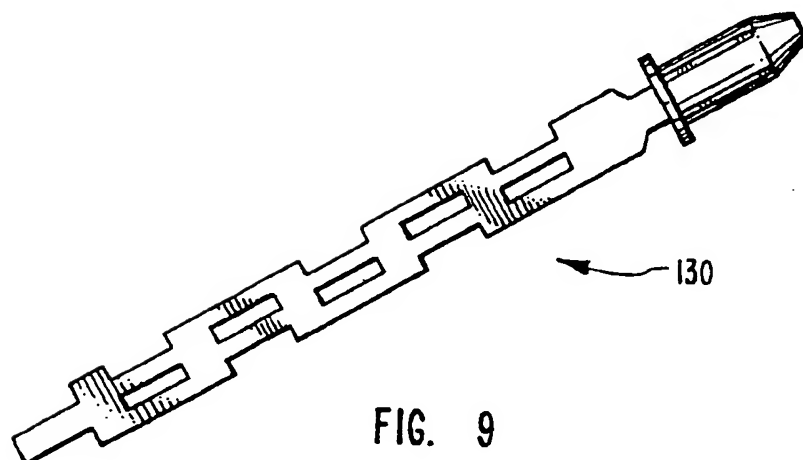
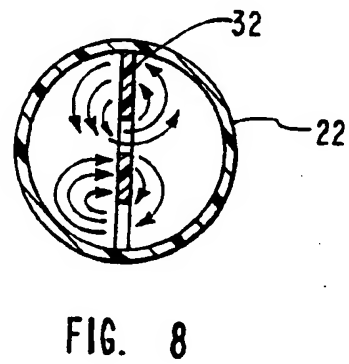
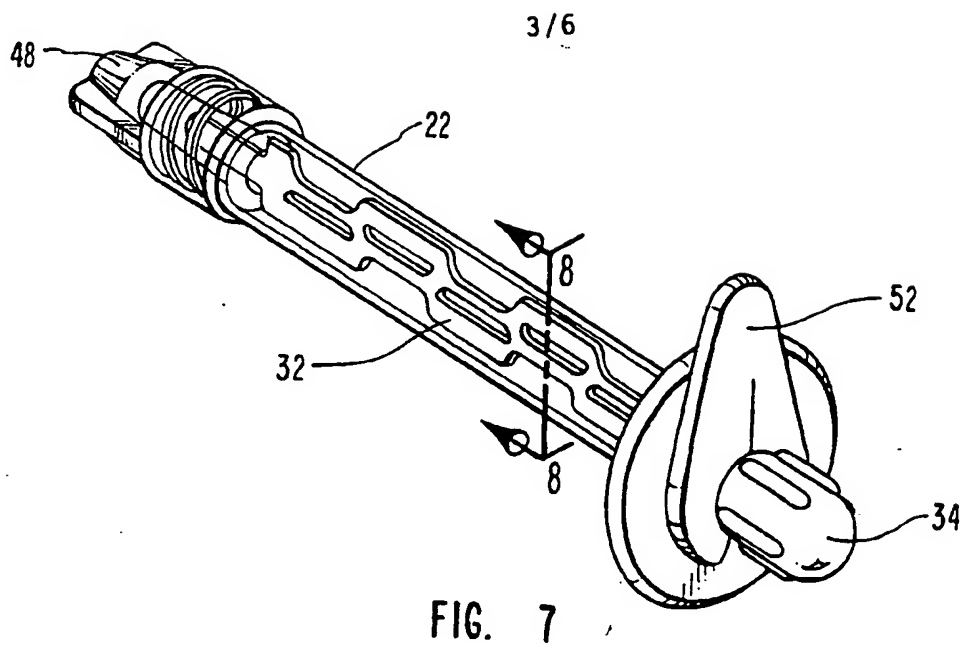


FIG. 5

FIG. 6





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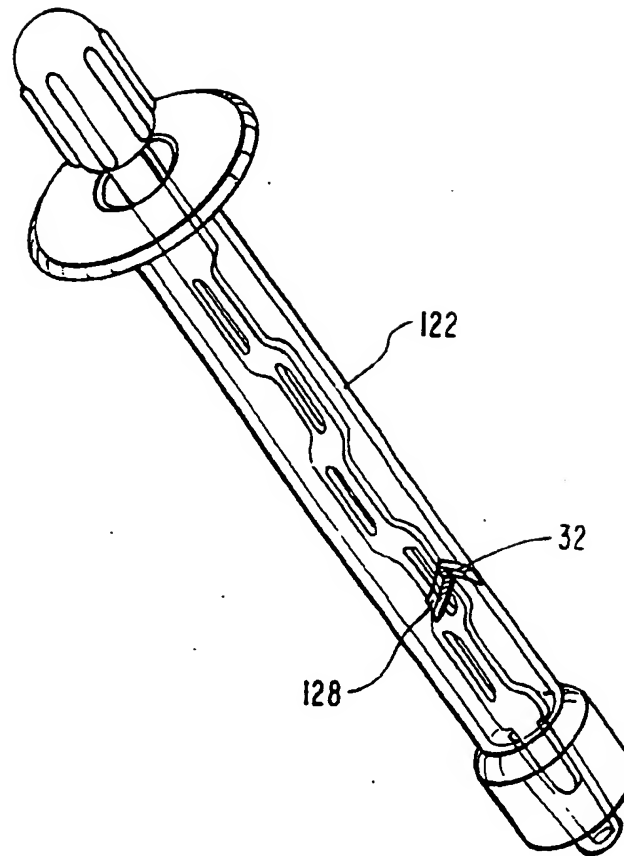


FIG. 10

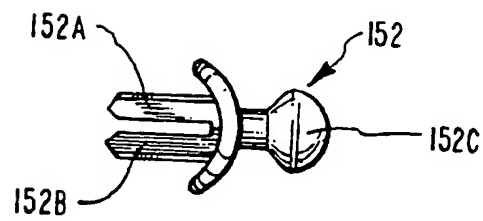


FIG. 11

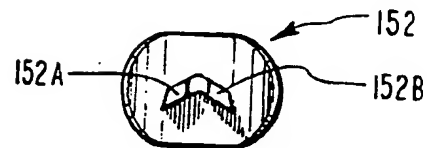


FIG. 12

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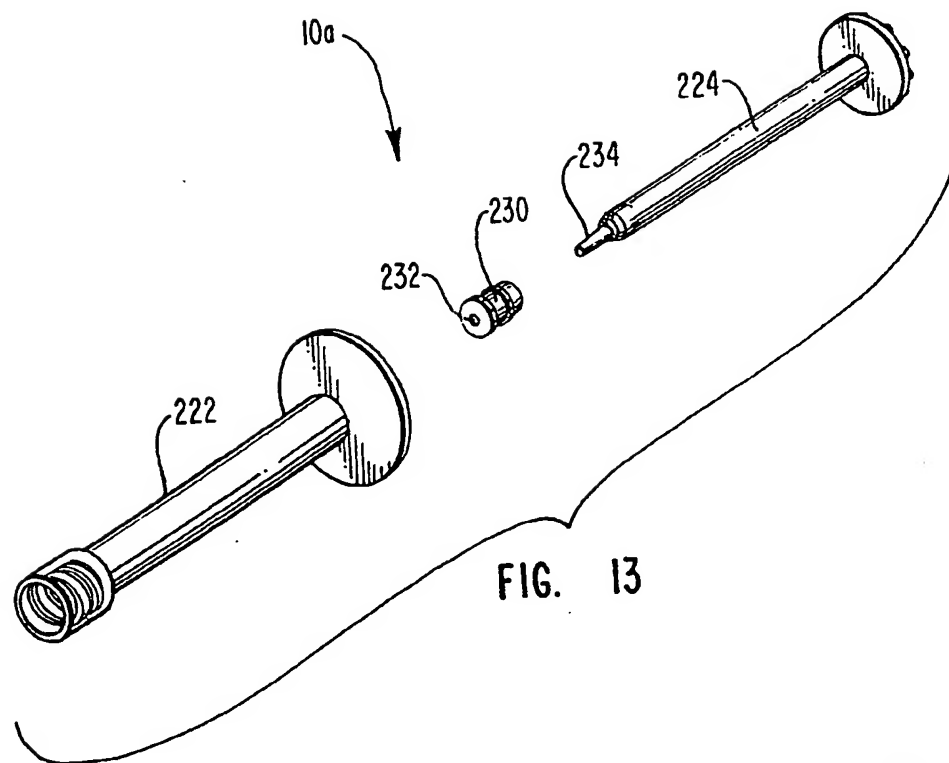


FIG. 13

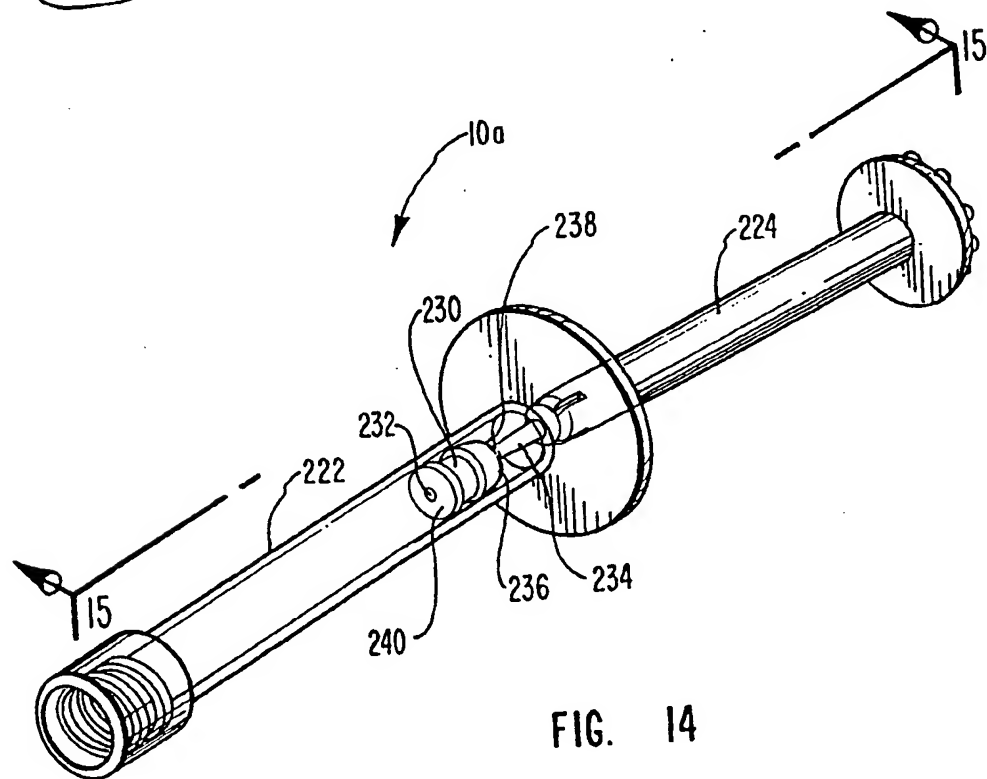
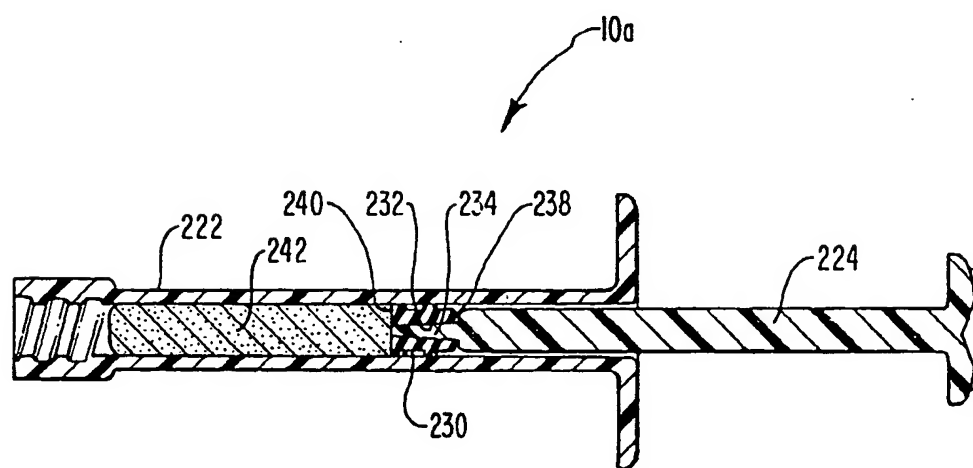
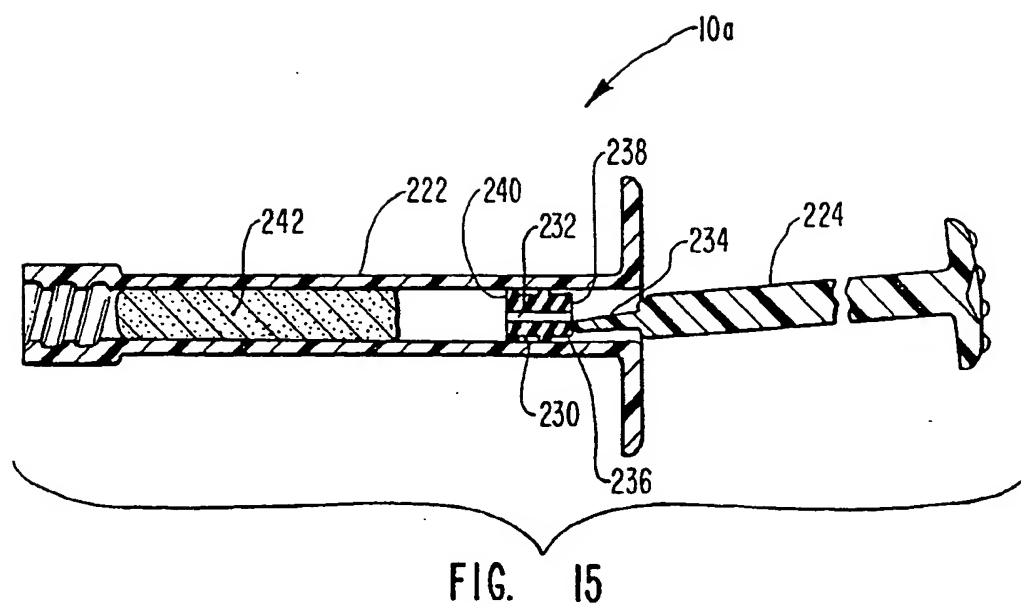


FIG. 14

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## INTERNATIONAL SEARCH REPORT

International application No.

PCT/US94/09983

**A. CLASSIFICATION OF SUBJECT MATTER**

IPC(5) :A61M 37/00

US CL :604/82

According to International Patent Classification (IPC) or to both national classification and IPC

**B. FIELDS SEARCHED**

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 222/83, 85, 145; 604/83, 87-91, 191, 411-416

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

NONE

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

NONE

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US, A, 4,392,850, (ELIAS ET AL.), 12 July 1983. See entire document.	1-25
A	US, A, 4,871,354, (CONN ET AL.), 03 October 1989. See entire document.	1-25
A	US, A, 4,979,941, (OGLE, II), 25 December 1990. See entire document.	1-25

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Further documents are listed in the continuation of Box C.

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See patent family annex.

* Special categories of cited documents:	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
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Date of the actual completion of the international search

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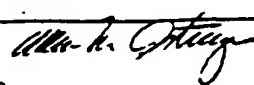
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